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PRE-APPEAL BRIEF REQUEST FOR REVIEW

Docket Number (Optional): 062219

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Application Number	Filed
10/506,979	09/08/2004

First Named Inventor: Alain DELACHE

Art Unit	Examiner
3743	Nihir B. Patel

Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.

This request is being filed with a notice of appeal.

The review is requested for the reason(s) stated on the attached sheet(s).
Note: No more than five (5) pages may be provided.

I am the

- ☐ applicant/inventor.
- ☐ assignee of record of the entire interest. See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96)
- ☒ attorney or agent of record. Registration number 32,878
- ☐ attorney or agent acting under 37 CFR 1.34. Registration number if acting under 37 CFR 1.34 _____

Signature

Stephen G. Adrian
Typed or printed name

202-822-1100
Telephone number

April 28, 2006
Date

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below*.

☐ *Total of _____ forms are submitted.

This collection of information is required by 35 U.S.C. 132. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11, 1.14 and 41.6. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the Application of: **Alain DELACHE et al.** Group Art Unit: **3743**

Serial Number: **10/506,979** Examiner: **Nihir B. Patel**

Filed: **September 8, 2004** Confirmation No.: **6948**

For: **APPARATUS TO ASSIST A PATIENT'S BREATHING WITH A VARIABLE RAMP PERIOD TO RISE TO TREATMENT PRESSURE**

Attorney Docket Number: **062219**
Customer Number: **38834**

REMARKS FOR PRE-APPEAL REQUEST FOR REVIEW

Commissioner for Patents
P. O. Box 1450
Alexandria, VA 22313-1450

April 28, 2006

Sir:

Applicants request a pre-appeal brief review because it is believed that the outstanding rejection is clearly improper and without basis or is clearly based on factual or legal error.

Claims 9-17 had been rejected under 35 USC §102(e) as being anticipated by Matthews et al. (US 2004/0187870). The Office Action asserts that Matthews et al. teaches:

(1) the comparator is connected to the ramp module;

(2) the comparator is able to determine whether a snore is occurring during the ramp period, the comparator sends the data in respect of snore detection to the ramp period module; and

(3) according to these data, the ramp module provides the control unit with the value of pressure that will speed up with respect to time during this ramp period, so that the rise of pressure at patient's mask is accelerated within the same ramp period.

These assertions are clearly erroneous.

(1) As shown in figure 2, the ramp module 118 is not connected to the comparator 140/142, the snore detection and monitoring modules, nor to any other detection or monitoring modules. The ramp module and other modules are directly connected to the control unit 106. The control unit 106 does not connect indirectly the ramp module to the detection modules or monitoring modules, but rules which of these modules will get control of the pressure delivery.

In fact, in the apparatus disclosed by Matthews et al., all the detection modules and monitoring modules and the ramp module are organized by layers set in a hierarchical order. Each control layer is competing for control of the pressure support system (paragraph [0069]). The control unit 106 gives control to the module which is the highest in the hierarchy.

(2) According to this hierarchical structure, a module will lose control if a higher priority module requests it. A module will get control only if no higher priority module is operating or has made a control request (paragraphs [0072] and [0070]). Each controller operates in a unique fashion based on the type of event/condition being treated (paragraph [0072], last sentence). This means that the ramp control layer and the detection layers do not cooperate.

It is further stressed in paragraphs [0074] and [0075], that machine based control layers among which is the ramp module (priority (2)), take control of the system only according to the condition of the pressure system, or in other words according to manual inputs. The lower priority layers (priority 4 to 8) take control only according to a monitored condition of the patient. For example, the snore control layer which regulates the pressure according to the snores

detected will operate only if the ramp control is not activated (see last sentence of paragraph [0079] and first sentence of paragraph [0095]).

Therefore, when the ramp is activated, any control request sent by any detection module (i.e., the snore detection module) is blocked by control unit 106 and is never transmitted to the ramp module.

(3) The ramp delivered by the ramp module according to Matthews et al. is a conventional pressure ramping technique (paragraph [0080]). The ramp duration can be time based or, as written in paragraph [0081], event based. However, in this part of the text, the term event based does not designate a detected event in the patient's breathing that occurs but the computation of a predetermined number of breathing cycles.

The ramp module 118 is not able to modify the ramping rise of pressure within one ramp period.

Please note that, during the ramp period, i.e., when the apparatus starts functioning the pressure applied to the patient rises progressively up to the pressure of treatment. Contrary to the apparatus of the invention claimed in claim 9, the apparatus of Matthews et al. does not teach that during the ramp period, data are sent to the comparator which determines if an event occurs and which during this ramp period, provides the control unit with a pressure value that will accelerate the rise of pressure at the patient's mask.

The snore layer increases the pressure of treatment when a snore is detected. This rise of pressure is of course not spontaneous and raises at a predetermined rate preferentially of 1 cmH2O (paragraph [0096]). The Examiner considers this as a ramp which is clearly erroneous.

Although this rise in pressure is linear, this is not what one of ordinary skill in the art calls "ramp", which is in fact the reason why this rise in pressure is not called a "ramp" in Matthews et al. Ramps are rises in pressure that are applied to the delivered pressure when the apparatus starts in order to enable the patient to fall asleep. The rise of pressure operated by the snore controller does not operate at the start of the apparatus but during the duration of patient sleep.

Most of all, the Examiner considers that because this rise of pressure is enabled by the snore module, it is a ramp modified according to the event that occurs in the patients breathing. However, when looking more closely at the operation of this rise, this rise of pressure is constant and never modified.

It is clear that the snore module only begins a rise of pressure when a third snore is detected. Once the pressure has increased, there is a lockout interval of one minute (paragraphs [0094] to [0096]). The aim of this lockout is to prevent another pressure increase if another snore occurs. Otherwise this would cause the snore controller to increase the pressure (first sentence of paragraph [0097]). The lockout prevents numerous snores in a short interval from inducing a too high pressure of treatment while the body has not yet been submitted to the first increase. A new increase of pressure (and not a speed up of an operating rise in pressure) will

appear in respect of additional snores only if the lockout interval has elapsed (see the second sentence of paragraph [0097]). This means that the snore module will only generate linear rises in pressure that can not be modified during one single raise of pressure. It can only generate several raises in pressure of same raising rates separated by time intervals where no increase is observed that is to say wherein pressure is constant.

Even if it can be considered that the ramp module of Mathews et al. provides a value of pressure which is a linear function of time wherein an increase coefficient is constant, Mathews et al. does not teach that said ramp module increasing that coefficient of a constant valve K_E as set forth in claim 10.

Thus, contrary to the Examiner's opinion, in the apparatus disclosed by Matthews et. al.:

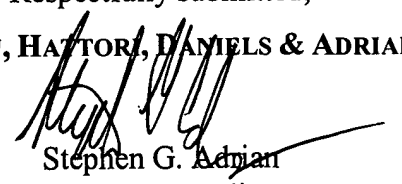
(1) the ramp module is not connected to the comparator;

(2) the comparator is not able to send the data in respect of events that occur in the patient's breathing to the ramp module; and

(3) the ramp module is not able to speed up the rise in pressure according to the event that occurs in patient's breathing.

Respectfully submitted,

WESTERMAN, HATTORI, DANIELS & ADRIAN, LLP



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